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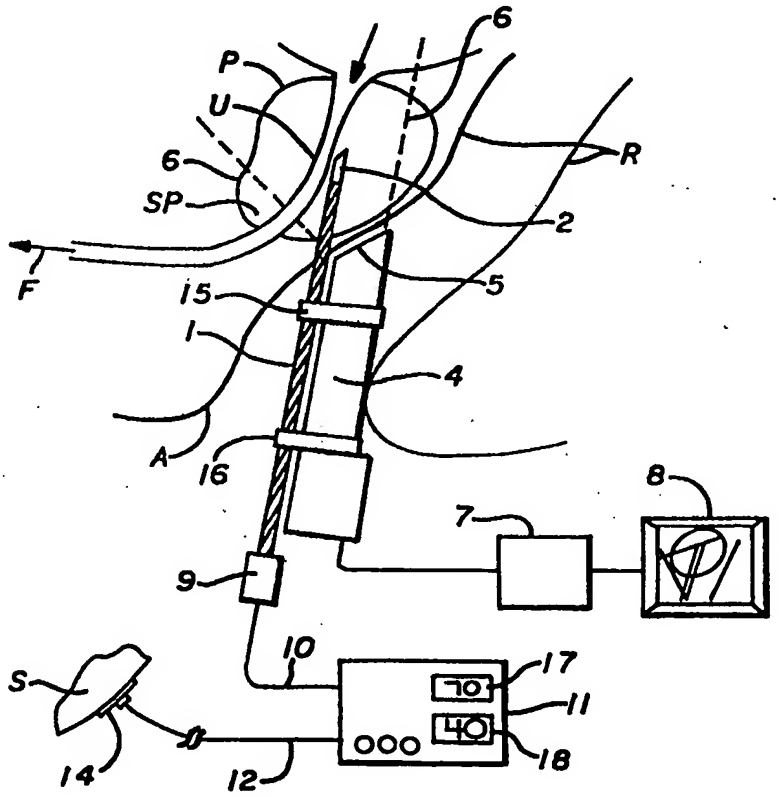
(54) Title: METHOD AND SYSTEM FOR PERFORMING TRANS-RECTAL RADIOFREQUENCY URETHRAL ENLARGEMENT

(57) Abstract

Relief of urethral obstruction is achieved by heat ablation of prostatic tissue by an ablation electrode placed in the central peri-urethral tissue of the prostate using a transrectal or a percutaneous approach. The electrode is coupled to a high frequency power supply to heat the prostatic tissue near the urethra. Image guidance of the electrode placement is monitored by an imaging device. Temperature is sensed at the electrode to control the high frequency heating energy and ablation process. The electrode has a pointed tip to help penetrate tissue of the patient such as rectal tissue or perineal tissue during insertion of the electrode tip near to the point of urethral obstruction. Several forms of electrodes, apparatus, and methods accommodate the specific objectives.



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METHOD AND SYSTEM FOR PERFORMING TRANS-RECTAL RADIOFREQUENCY URETHRAL ENLARGEMENT

FIELD OF THE INVENTION

This invention relates generally to advances in medical systems and procedures for prolonging or improving human life. More particularly, this invention relates to an improved method and system for alleviating urinary obstruction caused by enlargement of the prostrate by performing trans-rectal radiofrequency urethral enlargement.

BACKGROUND OF THE INVENTION

A majority of all males over 60 years old experience partial or complete urinary obstruction because of enlargement of the prostate. This condition usually originates from benign prostatic hyperplasia (BPH), which is an increase in cell mass near the urethra, or less likely, from prostate cancer. Both these conditions involve an increase in prostatic tissue mass, which in its increased state encroaches on the urethra and obstructs the urinary pathway.

In the case where urinary obstruction is caused by benign prostatic hyperplasia (BPH), a common treatment involves medical procedure using a medical side-cutting instrument and/or endoscope to surgically enlarge a passageway for urine flow through the prostate. The side-cutting instrument and/or an endoscope is passed through the penis into the urethra and is surgically used to remove prostate tissue and part of the urethra at the point of obstruction. This procedure is referred to as "Trans-urethral Resection of the Prostate" (TURP). This procedure although effective, is invasive and complicated. For example, it requires the use of anesthesia and substantial hospital care. Moreover, it is expensive and causes great discomfort and trauma to the patient. Chapter 18 entitled "Complications of Transurethral Resection of the Prostate," by R. Sunshine and M. Droller, of a book entitled *Urologic Complications, Medical and Surgical, Adult and Pediatric*, edited by Fray S. Marshall, in 1986, Yearbook Medical Publishers, elaborates on the various complications of the TURP procedure.

In the case where urinary obstruction results from prostatic cancer, surgical prostatectomies are commonly used to eliminate the obstruction. However, surgical

prostatectomies have serious side effects and risks, including impotence and urinary incontinence.

In recent years, less invasive systems and procedures that inflict less trauma on patients have been attempted. One such procedure called "Trans-urethral Needle Ablation" (TUNA) involves passing a radiofrequency (RF) instrument such as a catheter, cannula, sheath, or scope into the urethra. The radiofrequency (RF) instrument houses special radiofrequency (RF) electrode tips that emerge from its side, which are pushed out of the instrument along off-axis paths and into the prostatic tissue near the urethra. As a result of the various electrodes emerging from its side, the construction of such radiofrequency instruments are complex and expensive. By heating the prostate with radiofrequency (RF) power applied through the electrode tips emerging from the side of the radiofrequency (RF) instrument, the prostate tissue surrounding the urethra is ablated. A heat ablation is performed at multiple locations outside the urethra to provide a series of ablations outside it. Thus, by using the TUNA system and procedure, the urethra is essentially preserved and the series of ablations cause the prostate tissue to die and necrose. Subsequent to heating, the necrotic tissue is absorbed by the body or excreted, thereby reducing the tissue mass outside the urethra, which consequently reduces the urethral obstruction. For further explanation of this system and procedure, one can consult a research paper published by Goldwasser, et al., entitled "Transurethral needle ablation (TUNA) of the prostate using low-level radiofrequency energy: an animal experimental study;" Eur. Urol. 1993: 24; 400-405; and a research paper published by Schulman, et al., "Transurethral needle ablation (TUNA); safety, feasibility, and tolerance of a new office procedure for treatment of benign prostate hyperplasma;" Eur. Urol. 1993; 24; 415-423. Also, product literature on the TUNA system available from a company named Vitamed, Inc., of Menlo Park, California, carries some description.

The TUNA system and procedure is generally used to relieve urethral obstruction caused by benign prostatic hyperplasia (BPH). It favors a transurethral approach because the target tissue to be ablated by radiofrequency (RF) power surrounds the urethra and is generally near to it. However, again, although the TUNA system and procedure is effective, it requires epidural or general anesthetic, and generally causes the patient great discomfort and pain. Moreover, the TUNA procedure is medically and technically very complex for surgeons to perform, requiring a complicated and expensive catheter or sheath or radiofrequency (RF)

electrode system to perform it. Also, it is a relatively blind procedure in the sense that the ends of the radiofrequency (RF) electrodes emerging at the side of the radiofrequency electrode system, once they penetrate the target tissue cannot be seen. Nor is there any technique for providing a visual representation of them. Furthermore, the TUNA system and procedure attempts to leave the urethra area intact and uninjured by the application of radiofrequency (RF) heating, which is difficult to achieve, making its outcome uncertain. The TUNA system and procedure causes scratching of the urethra, bleeding or irritation from a cystoscope, cannula, catheter, or tissue-piercing electrode tips passed into the urethra.

Another system and procedure contemplated by Onik, et al. is described in their research paper entitled "Transrectal ultrasound-guided percutaneous radical cryosurgical ablation of the prostate;" Cancer 1993; 12; 1291-1299. This technique is utilized for the treatment of prostrate cancer and involves disposing cryogenic (freezing) probes in the prostate for ablating the cancer cells. Onik, et al., propose passing a cryogenic probe trans-perineally (through the perineum) into the prostate. At the same time, an imaging ultrasonic probe is passed through the rectum and is used to visualize the position of the cryogenic probe and the volume of cryogenic ablation in the prostate. This technique requires use of cryogenic probes (also referred to as cryo-probes) having a relatively large cryogenic probe diameter. The cryo-probes are complex in construction and operation and require elaborate cooling and thawing cycles, making the procedure complicated and expensive. It is technically challenging and critical to maintain precise temperatures at the target tissue area to prevent hemorrhaging when removing the probe and freezing of sensitive rectal mucosa tissue.

One more recent procedure contemplated and reported by McGahan, et al., in their research paper entitled involves transrectally placing a radiofrequency (RF) electrode into the prostate of a dog under rectal ultrasound guidance. Their intent was solely to explore the feasibility of ablating cancerous tumors within the peripheral region of the prostate. Their research treated only normal animals and no ablation of cancer tissue was actually performed. McGahan, et al., hoped to prevent radiofrequency (RF) heat ablation of the urethra (which is located centrally in the prostate). To achieve their objective, they suggested that the urethra should be irrigated with saline solution, using a catheter, to prevent radiofrequency (RF) heat damage to the urethra and peri-catheter, urethral tissue. They concluded that their system and procedure was impractical for ablating prostate cancer cells, because the radiofrequency (RF)

lesions were limited to 1 to 1.5 cm in diameter, which they felt would be too small to adequately treat malignant cancer cells.

Generally, prostate cancer primarily occurs in the peripheral (non-central) zone of the prostate. It is often multi-focal, near the rectal wall, and near nerves controlling potency. Recognizing the restraints and delicate circumstances, McGahan, et al., were discouraged by the results of their research. They concluded that their technique may be applicable to only a small percentage of prostate carcinomas, specifically, those that are small and can be imaged by ultrasound. In their paper, they emphasized their concern for preventing radiofrequency (RF) heat damage to the rectal mucosa tissue. Thus, as a result of their efforts to treat prostate cancer, which is predominantly located in the peripheral non-central part of the prostate, they focused their research efforts on the peripheral, peri-rectal regions of the prostate. Their research did not contemplate radiofrequency (RF) ablation in the central peri-urethral region to produce an ablation cavity near the urethra or to ablate the urethra itself. In fact, they explicitly sought to avoid injury of the urethra by avoiding treatment of peri-urethral tissues. Their method and objectives were directed to cancer and disadvantageous for treatment of BPH or for treating urethral or periurethral tissues by radiofrequency (RF) ablation to relieve urinary obstruction.

It should be recognized that the theory behind and practice of radiofrequency (RF) heat lesion has been known for decades, and a wide range of radiofrequency (RF) generators and electrodes for accomplishing such practice exist. For example, equipment for performing heat lesions are available from Radionics, Inc., located in Burlington, Massachusetts. Radiofrequency (RF) ablation is well known and described in medical and clinical literature. To that end, a research paper by E.R. Cosman, et al., entitled "Theoretical Aspects of Radiofrequency Lesions in the Dorsal Root Entry Zone;" Neurosurgery; 1984; Volume 15; No. 6; 945-950, describing various techniques associated with radiofrequency lesions, are incorporated herein by reference. Also, a research paper by S. N. Goldberg, et al., entitled "Tissue Ablation with Radiofrequency: Effect of Probe Size, Gauge, Duration, and Temperature on Lesion Volume;" Acad Radiol; 1995; 2; 399-404, describe techniques and considerations relating to tissue ablation with radiofrequency.

However, as such techniques have never been performed in the periurethral region (the region surrounding the urethra or the central prostate region), for the reasons discussed above,

an effective technique for performing trans-rectal radiofrequency urethral enlargement for purposes of alleviating urinary obstruction caused by enlargement of the prostrate is desirable.

SUMMARY OF THE INVENTION

The present invention is directed to a system and procedure for radiofrequency (RF) heat ablation of prostatic tissue by use of an radiofrequency (RF) electrode, which is advanced using a transrectal or percutaneous (such as transperineal) approach to reach the periurethral region, i.e., the region surrounding the urethra or the central prostate region, for the treatment of benign prostatic hyperplasia (BPH) with the associated alleviation of urethral obstruction. The system and procedure of the present invention are different from any of the systems and procedures discussed in the background section. The advantages of the present system and method reside in their combined simplicity, economy, control, consistency, and clinical effectiveness.

As one example, urinary bladder outlet obstruction can be effectively treated using the present system and technique, which is minimally invasive. The technique of the present invention involves transrectally inserting a radiofrequency (RF) electrode into the central region of the prostate, proximate to the region of the urethra. This avoids the more difficult and uncomfortable transurethral approach of the TUNA system procedure discussed above, and may be done without need for passing one or more side-outlet radiofrequency (RF) electrodes into the prostatic tissue surrounding the urethra. The present system and procedure includes image guidance, which may be performed in a variety of ways including ultrasound, CT, MRI, fluoroscopy, X-rays, or other well-known imaging techniques.

In accordance with one embodiment, a radiofrequency (RF) electrode may be passed through the rectal wall under ultrasound imaging guidance, and its exposed radiofrequency (RF) tip placed in the prostate, near the portion of the urethra, which is being obstructed by the enlarged prostate tissue volume (for example, in the case of benign prostatic hyperplasia (BPH) or some types of prostatic cancer). The transrectal approach avoids passage of a catheter electrode into the penis and urethra, as in the TUNA method. Also, in contrast to the TUNA technique, needles can be placed in a patient's body transrectally (usually done when performing a biopsy) without the need for anesthesia.

It enables patients unable to tolerate the TUNA system and procedure to receive

radiofrequency (RF) ablation treatment. For example, such patients could be those unable to tolerate anesthesia because of old age and frail health.

The present system and procedure has the advantage of controlling the positioning of the electrode, by direct imaging techniques, reducing the risks associated with the blind TUNA procedure.

According to the present inventive technique, a radiofrequency (RF) heat lesion is made in the periurethral region, i.e., near or on the urethral tissue, to induce necrosis of the prostate tissue near the urethra and/or of the urethra itself. This induces a cavity to be formed in the central region of the prostrate in the patient's body, a few days after the procedure is performed. The cavity provides direct communication to the urethra. In accordance with one example, lesion sizes of 1 to 2 cm diameter can be made, which induce similar sized cavities to be formed, thereby enlarging the urethral passage. These exemplary lesion sizes, similar to those made by the TURP procedure, prove to be adequate by using the present system and procedure.

It should be noted that in contrast to McGahan et al.'s conclusion that such lesion sizes are inadequate for ablation of prostate carcinomas, the lesion sizes are adequate. Also, the present technique avoids heat injury of the urethra and the necessity for irrigation and cooling of the urethra by saline.

These features and advantages as well as others of the present method and system will become apparent in the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which constitute a part of the specification, embodiments exhibiting various forms and features hereof are set forth, specifically:

FIGURE 1 is a schematic diagram showing the system for performing transrectal radiofrequency (RF) ablation of the central prostate with ultrasonic imaging according to the present invention;

FIGURE 2 illustrates the procedure or technique by which a radiofrequency electrode is placed near a point of urethral obstruction in the prostate to make an radiofrequency (RF) lesion according to the present invention;

FIGURE 3 shows a cavity in the prostate induced by the system and method of the

present invention;

FIGURE 4 shows a flow chart of the system and process in accordance with the present invention;

FIGURE 5 shows another embodiment of a prostate ablation electrode with multiple temperature sensors in accordance with the present invention;

FIGURE 6 shows CT or MR image guidance of an radiofrequency (RF) electrode according to the present invention;

FIGURE 7 illustrates an exemplary electrode for prostatic ablation according to the present invention; and

FIGURE 8 shows an ablation electrode and satellite temperature monitors in accordance with the present invention.

DESCRIPTION OF SOME PREFERRED EMBODIMENTS OF THE INVENTION

Referring to Figure 1, in accordance with the present method and system, a radiofrequency electrode 1 is inserted through the rectal wall R of a living body, such as a patient, into an operative field within the patient's body, specifically, including the prostate gland P. The tip of the electrode 2, which is electrically uninsulated, is placed proximate to the urethral tube U, which drains the urine from the bladder B in the living body. The electrode 1 may have an insulative shaft portion indicated by the hatched line in Figure 1. It is inserted through the anal opening A and penetrated through the tissue of the rectal wall R. This is described and referred to as the transrectal approach of a radiofrequency (RF) electrode into the prostate. The electrode tip 2 preferably has a sharpened point for ease of penetration through the rectal wall R and prostate tissue itself.

Also shown in Figure 1 is an ultrasonic imaging device 4, which at its proximal end has an imaging head 5 that is placed near the rectal wall R or against it. The ultrasonic imaging device 4 may be any common tool used in diagnostic medicine and is widely available. For example, Accuson Inc, located in Mountain View, California, provides ultrasonic imaging devices. The imaging head 5 may take the form of an ultrasonic scanning transducer (also referenced by reference numeral 5). With the ultrasonic imaging device 4, any desired area of tissue may be imaged. In other words, the ultrasonic imaging device 4 generates a visual representation of any desired area of tissue.

Considering the example illustrated in Figure 1, the area or sector of tissues falling within the region bounded by dashed lines 6 is scanned by the ultrasonic scanning transducer to generate a visual representation. The illustrated area or sector of tissue includes the rectal wall, prostate P, and urethra U. The ultrasonic scanning transducer 5 also observes the radiofrequency electrode 1, which is disposed within the area being scanned. The ultrasonic scanning transducer 5 is connected to an ultrasonic imaging processing unit 7 and a display unit 8, as is common practice. The display unit 8 serves to provide real time ultrasonic images of the prostate with the radiofrequency (RF) electrode tip 2 placed near the urethra U. In this way, ultrasonic image guidance is used to carefully locate the electrode at the appropriate point, for example, the central region of the prostate P, proximate to the urethra U, and if desired away from particularly sensitive areas of the prostrate such as its apex AP and sphincter SP regions.

The radiofrequency electrode 1 has an electrical connection, illustrated by 9, at its proximal end (to the surgeon), which is connected by a wire or cable connection 10 to a radiofrequency generator or high frequency energy source referenced by numeral 11. The radiofrequency generator may be an electronic unit with, for example, a radiofrequency, microwave, or other high frequency power supply that can deliver high frequency voltage to the electrode tip 2.

In accordance with known technology for generating radiofrequency (RF) lesions, described in the articles by E. R. Cosman et al., which are incorporated herein by reference, high frequency voltage applied through the exposed tip 2 produces a heated region around it, which produces a heat lesion or ablation zone around that exposed tip 2. Yet another recent paper by Solboati, et al., entitled "Percutaneous US-guided Radio-Frequency Tissue Ablation of Liver Metastases: Treatment and Follow-up in 16 Patients;" Radiology; 1997; 202: 195-303, describe techniques and considerations relating to tissue ablation, which research paper is also incorporated herein by reference. The size of the ablation zone or heat lesion is increased by increasing the power from the generator source 11 that is applied to the tissue. The size of the ablation zone varies with an increase of the temperature around the electrode 2 (unless the electrode tip is cooled).

Also shown is another cable 12 from the generator which goes to a reference electrode 14 that may be in contact with a portion of the patient's skin or body, illustrated by S. This

electrode serves, as is common practice, as a reference or return electrode for the radiofrequency current emitted from the radiofrequency (RF) electrode 2. Examples of radiofrequency (RF) lesion generators and radiofrequency (RF) electrodes can be found in the product literature of Radionics, Inc., Burlington, Massachusetts. The radiofrequency (RF) generator may have temperature meters 17 or other lesion parameters readouts 18 illustrated by a digital meter reading, for display of power, current, voltage, impedance, or other parameters associated with the radiofrequency (RF) lesion process (as described in the paper by Cosman, et al) incorporated herein by reference.

To give a specific illustration to reduce urinary blockage in accordance with Figure 1, a radiofrequency (RF) electrode 1 with 18 gauge diameter is insulated with an insulating coating similar to that used on the Radionics radiofrequency (RF) electrodes. An exposed electrode tip 2 of approximately 5 to 20 mm is used, and the tip electrode is a sharpened point to allow penetration of the rectal wall R and the prostate tissue P with trocar, conical, or bevel point. The electrode tip 2 may have an overall configuration that resembles a needle. In accordance with one embodiment, the electrode tip 2 is self-contained and sealed. In accordance with another embodiment, the electrode tip 2 has an outer cannula with an inner stylet to initial insertion. The electrode tip 2 also comprises a temperature sensor or alternatively, it may have a temperature-monitoring probe that is inserted into the cannula once it is penetrated in the tissue. By carefully placing the radiofrequency (RF) electrode near the central region of the prostate and near the urethra U, effective ablation of the prostate tissue on and about the region of the urethra to induce relief of a urinary obstruction (due to BPH occlusion of the urethra) is accomplished.

In accordance with one embodiment, a heat lesion of desired size is formed by controlling the temperature in the prostate tissue immediately surrounding the radiofrequency (RF) electrode tip to approximately 90°C. With this temperature, an ablation volume having a diameter of approximately 1 to 1.5 cm is made. The size of the heat lesion is visualized on CT after the heat lesion is made.

In accordance with other embodiments, depending on the lesion sizes desired, other electrode tip temperatures or prostate tissue temperatures ranging between 50 to 100°C, are used. The desired lesion sizes are determined (for example 0.3 to 5.0 cm) depending on the size and geometry of the patient's prostate or urethra or other clinical considerations.

The lesion generator 11 has a power range from 0 to approximately 50 watts, although only 20 watts or less is generally adequate to achieve the temperature cited above. The electrode tip 2 has a temperature sensor built-in within its electrode tip 2, which is a thermistor, thermocouple, or other type of temperature sensor. The temperature sensor is coupled via connection wires extending inside the electrode shaft 1 to the lesion generator and meter 17 to enable monitoring of the temperature. The electrode shaft 1 in accordance with one embodiment is approximately 20 to 25 cm in length. In other embodiments, 5 to 35 cm lengths may be used. It should be recognized that varying sizes, geometries, electrode tip configurations, etc., may be used for the radiofrequency (RF) electrode 1 to produce radiofrequency (RF) lesions.

An ultrasonic monitor or detector 4 such as one called the Accuson XPoXP monitor available from the Accuson company, located in Mountainview, California, may be used to provide images on a display screen 8. Carrier elements 15 and 16 enable guidance of the radiofrequency electrode shaft 1 proximate the ultrasonic detector 4 so that an ultrasonic image of the electrode shaft 1 and electrode tip 2 and their movement can be seen within the prostate P as visualized on the screen display 8.

It should also be recognized that a variety of configurations of the carrier elements 15 and 16 are possible. A transducer housing in which the ultrasonic detector 4 is housed may incorporate a guidance system within the housing or may attached to a separate one. The positioning of the electrode tip 2 next to, or even against, or through the urethra U in accordance with the present invention can be clearly visualized in this way. The surface of the electrode tip 2 or the electrode shaft is preferably roughened, scored, or otherwise configured to make it more visible on ultrasonic imaging. For example, in some embodiments the surface of electrode tip 2 is sand blasted or configured with grooves in it. In other embodiments, the electrode tip 2 is coated with a film or mottled material. In yet other embodiments, the electrode tip 2 is configured with pits or cavities to trap air for differential sonic index of refraction or sonic reflectance to enable visibility using ultrasound, CT, or MR imaging techniques.

Figure 2 shows a diagram illustrating the manner in which a thermal lesion is made by a radiofrequency electrode in the peri-urethral zone. Generally, a patient's bladder B is illustrated, which communicates with the patient's urethra U. By way of example, a urinary

obstruction is show by the urethral constriction and narrowed region UR. On either side of the urinary obstruction UR, the urethra U is illustrated assuming its normal size. Flow of urine is indicated by vector arrows F. The radiofrequency electrode shaft 1, as shown, is advanced to penetrate the prostate P with its electrode tip 2 lying within the peri-urethral region, proximate the urethral obstruction UR. Radiofrequency voltage is applied to the electrode to cause radiofrequency (RF) current to flow from the exposed electrode tip 2 into the peri-urethral tissue. Radiofrequency (RF) energy dissipation causes a heating zone to occur around the electrode tip 2, thereby engulfing the urethra and peri-urethral tissue. In this embodiment, the dashed line 20 is used to illustrate a typical isothermal surface area or a surface area of constant temperature. By maintaining a desired temperature for a desired time, all the tissue in that region is killed or ablated. An example of a desired temperature to kill prostate tissue is approximately 50°C maintained for a length of time of 6 minutes. It should be recognized that variations, depending on the desired outcome, is possible.

An isotherm surface area corresponding to the tissue ablated, therefore, is an indication of the area in which the cells are dead. At 50°C or higher temperatures, tissue necrosis in the isotherm surface area is induced. Liquefaction of the treated tissues occurs within days from the day of the treatment. If such an isotherm surface area (corresponding to ablation or necrosis), as illustrated by reference numeral 20, engulfs the urethral restriction UR, then in a matter of days the entire peri-urethral zone within that isotherm surface area is obliterated and liquefied. The flow of urine F may then carry the liquefaction and debris from the necrotic tissue away and out of the body through the urethra.

Figure 3 illustrate the effects induced by the system and method for radiofrequency (RF) urethral enlargement by thermal ablation in accordance with the present invention. The inventive system and procedure obliterates the area or region within the isotherm thermal surface boundary of necrosis and induces a cavity 24 in communication with the urethra U. Therefore, an enlarged urethral passageway U is formed.

By way of further explanation, the urethral wall and the peri-urethral tissue that was in the area or zone of necrosis is liquefied and carried away by urine flow F. As the urethral cross-sectional area is increased, the impedance to flow of urine is substantially reduced and the flow vector F is increased in magnitude, restoring normal voiding function or improving voiding rate. The body reacts to this procedure by creating an epithelial layer of cells, within a

matter of a few weeks to cover the interior surface of the cavity 24.

During the process of carefully positioning the electrode tip 2 relative to the urethra (as illustrated in Figure 2), a visual representation is relayed by the ultrasonic detector 4 and displayed on the ultrasonic screen 8 (Figure 1). The electrode tip 2 is thus carefully maneuvered and centrally located within the prostate P. As indicated before, roughening the surface of the electrode tip 2, improves the ecogenic visualization. More simply stated, the electrode tip 2 is more perceived in the ultrasound image compared to the insulated portion of the electrode shaft 1. The is allows the exposed electrode tip 2 to be safely guided and located in the peri-urethral central zone, away from the peripheral region of the prostate, and especially, for example, delicate regions close to the rectal wall, sphincter, apex, or peripheral nerves.

Because a typical isotherm surface area 20 is created in a generally central area, the peripheral annulus of the prostate acts as a natural margin of safety or thermal buffer zone for the critical organs, which typically lie within the peripheral region or just outside the prostate P.

Referring now to Figure 4, a flow chart is shown to illustrate the process of trans-rectal urethral enlargement by using a radiofrequency electrode. The procedure starts at block 27, which represents the step of inserting a radiofrquency (RF) electrode 1, such as any one of those described above, trans-rectally (or otherwise through the skin such as the perineum) into the prostate P, as illustrated in Figure 1. The insertion and guidance of the radiofrequency (RF) electrode 1, is visually represented and observed by an ultrasonic CT, MR, PET, X-ray, or other imaging device, as illustrated by block 30. By way of one example, to visually assist with guiding the radiofrequency (RF) electrode 1 and its exposed tip into the central region of the prostate P and peri-urethral tissue. This step in the procedure is illustrated by block 28. CT, MRI, or other imaging modalities may be substituted for ultrasonic imaging represented by the block 30. To evaluate the proper location where the radiofrequency (RF) electrode 1 should be located near the urethra, data on the electrode tip, such as its tip length exposure etc., is taken into consideration. Related computations may be performed. The variations in radiofrequency voltage, current, or power applied to the radiofrequency (RF) electrode 1, are represented by block 29. The actual parameters of the radiofrequency (RF) power delivered to the radiofrequency (RF) electrode 1 may be recorded and displayed. The chosen or desired

levels for the heating may correspond to prescribed current, voltage, power, temperature or time of exposure of the electrode tip (or other temperature sensors placed in the prostate at various positions). Knowledge of these radiofrequency (RF) parameters and the geometry and size of the electrode tip assist in guiding the surgeon as to the size of the lesion and resultant cavity that is produced. For example, it may be known from clinical experience that a certain size ablation can be induced for a certain electrode geometry type with a known value of rf power, current or voltage, or alternatively, a known temperature. As represented by block 31, these radiofrequency (RF) parameters are monitored, such as monitoring the tip temperature, tissue temperature near to or remote from the tip, power, current, voltage, impedance, and other electrical parameters associated with the lesion process. Monitoring may be accomplished by placing separate or plural temperature sensors or electrode in or near the prostate for multiple thermal sensor readings. Measurement of such parameters is accomplished by the lesion generator systems of Radionics (Burlington, Massachusetts).

The construction of the radiofrequency (RF) electrode for trans-rectal, trans-perineal, or abdominal approach to the central prostate can take various forms and embodiments, which are now described. The electrode may have a pointed tip with conical, beveled, trocarred, or other shapes. Alternatively, the electrode may come as part of a set with sharpened introducing cannula, and the electrode tip may not be pointed but rather rounded if the introducer is used for penetration of tissue. The radiofrequency (RF) electrode may have multiple side-outlet tips, arrays of electrodes, cooled tip electrodes, bipolar electrode configurations, curved tips, and so on. For instance, the electrode 2 may include side-issuing electrodes to enlarge the lesion volume off the electrode tip 2 axis as with the Radionics Tew or ZHK electrodes. There may be fluid flow cooling within electrode tip 2 to cause an enlarged lesion size within the prostate.

In accordance with another embodiment of the present invention, the radiofrequency (RF) electrode may not include a temperature sensor. The correlation of an ablation size desired to a certain electrode tip geometry may be determined by considering RF generator parameters such as power output, voltage, and current. Generally, it can be determined that ablation temperatures of greater than 50°C in prostate tissue can be induced, for example, for RF power or RF current levels greater than known amounts. This information can be used by clinicians to induce sufficient ablation sizes to alleviate urinary obstructions, depending on the

clinical circumstances.

The radiofrequency (RF) electrode itself may be self-contained, having a unitized metal shaft such as tubular stainless steel or other material with an enclosed, sealed tip pointed or unpointed. Inside the electrode tip 2 may be a thermocouple, thermistor, or other temperature sensor. The sensor may be in the interior of the tip or integral with the surface of the tip. The electrode shaft 1 may be electrically insulated by various materials, sheaths, or coatings, such as epoxy, Teflon, etc. The hub of the electrode may be tubular or shaped to best conform to the operator's fingers as he inserts it trans-rectally or trans-perineally.

To be guided by an ultrasonic imaging device 4 placed in the rectum, the shaft 1 of the radiofrequency electrode may be approximately 200 mm or more. The tip 2 of the radiofrequency (RF) electrode, which is uninsulated and conductive for the radiofrequency (RF) heating, may have properties that make it more visible on ultrasonic scanning. For example, there may be a step-down from the insulation to the conductive tip diameter that is visible on the ultrasonic image. As mentioned before, the electrode tip 2 may be roughened, scored, or sandblasted so that it is more ecogenic and visible. There may be notches or other structures on the tip to differentiate the uninsulated tip from the insulated shaft as seen on image scan data. The radiofrequency (RF) electrode may be a composite of a pointed cannula with a pointed stylet that can be inserted into the cannula during the penetration of the cannula into the prostate. Once properly in place the stylet may be removed and another probe, such as a thermal sensing probe or radiofrequency probe, may be inserted within the lumen of the cannula for the radiofrequency (RF) coupling to the radiofrequency (RF) generator for heating the tissue and for thermal monitoring of the heating process. The electrode may be made of MRI or CT compatible materials so that it is visible in MRI or CT imaging without substantial artifacts.

Figure 5 illustrates another embodiment in accordance with the present invention. The electrode tip 2 is located in the peri-urethral or near urethral tissue of the prostate P. It has been inserted through the rectal wall R. There can be one or more temperature sensors within the electrode. For example, a temperature sensor is indicated by reference numeral 35 is located at the exposed tip 2. There may be other temperature sensors as indicated by reference numerals 36 and 37 at different locations or orientations on the electrode body. For example, temperature sensor 36 may be at the portion of the electrode which is insulated

(indicated by the hatched shading). It may be a known or calibrated distance from the electrode tip 2 or the temperature sensor 35 within the tip so that a gauge of the isotherm distribution away from the tip can be determined by the operator. Yet another temperature sensor 37 may be located further up the shaft of the electrode again, at a calibrated on non-calibrated distance.

A multiplicity of such temperature sensors can be used to provide an indication of the thermal distribution during the heat ablation process. For instance, a sensor placed near the rectal wall, such as illustrated by reference numeral 37, could detect if the rectal wall is sufficiently cool to prevent thermal damage. The temperature sensors may be movable or fixed within or on the outside of the electrode shaft 1. For example, a temperature sensor may be mounted on a secondary sheath which encloses the electrode shaft and can be moved longitudinally along the shaft so as to approximate the rectal mucosa R.

In this way a temperature sensor can be deliberately placed on the rectal wall during the radiofrequency (RF) ablation process to monitor its safety. Alternatively, a probe that is movable within the electrode shaft 1 may have a temperature sensor, and it can be positioned in a calibrated or measurable way along the shaft of the electrode so as to bring it to a known positive relative to the electrode tip 2. Such an internal temperature sensing shaft may have a multiplicity of thermocouples or thermistors on it at known distances so that the operator can obtain a readout of the temperature distribution at incremental positions from the electrode tip 2 up to other positions along the shaft 1, thus, being able to gauge the distribution of thermal ablation as it proceeds.

Figure 6 illustrates another embodiment of the system and method in accordance with the present invention for visually guiding the radiofrequency (RF) electrode into the prostate P. A tomographic scanner 40, such as a CT, MR, PET, X-ray, or other scanner, takes image representations of the prostate P, and/or urethra U, as well as the electrode 1 as its tip 2 is placed near the urethra or anywhere in the prostate as the clinical situation may dictate. Portable or open CT or MR scanners may be used for the imager 40. Image data from 40 are developed and processed by a computer or electronic unit. The data may be displayed on display unit 42 such as a CRT, liquid crystal display, etc. Image of the prostate 43, urethra 45, electrode 44, etc., may be displayed on a display unit referenced by reference numeral 42 in either 2 dimensional (2D) or 3 dimensional (3D) views, as desired. These images visualize and

guide placement of the radiofrequency (RF) electrode 2 relative to the prostate P and neighboring vital, organs. Also, these images assist with creating suitable sizes of the radiofrequency (RF) heat ablation isotherms (not shown in Figure 6, but as illustrated in Figure 2). MRI images are now able to "see" the radiofrequency (RF) heat isotherms as they are being constructed, and so real-time, interactive radiofrequency (RF) ablations for benign prostate hyperplasia (BPH) are possible.

A control nit or preplanning workstation 49 may be coupled to generator 11 and/or image data controller 41 to guide the procedure in accordance with preplanned paths, lesion sizes, radiofrequency (RF) lesion parameters, etc., so that the generator and images are integrated and the lesion can be monitored and controlled based on the image of the anatomy and/or lesion/heat image.

Figure 7 illustrates another embodiment of the present system and procedure in accordance with present invention comprising an elongated electrode with shaft 1 and exposed conducting tip 2 with a sharpened or pointed tissue-piercing tip 51. The shaft length L is schematically illustrated and for trans-rectal or percutaneous insertion, as stated above, a length of approximately 200 mm or more is suitable to reach the central region of the prostate. The exposed tip length TL may have varying dimensions from a few millimeters up to 20 or 30 mm or more. The length TL may be variable and adjustable on the electrode by means of a sliding hub or insulated cannula with exposed tip extending from it or it may be fixed and selectable by the clinician at the time of surgery according to the clinical indications and the size of the prostate or urethral obstruction.

Also shown in Figure 7 is a hub element 52, which may be fixedly attached to the shaft 1 or adjustable and settable to the shaft 1, as for example with a set screw. The hub 52 has an appendage, scalloped, contour, finger tab, or other convolutions indicated by 53 which enable the surgeon's fingers F1 and F2 to grip the hub 52 and move it forcibly in the direction aligned approximately with the shaft or angulating relative to the shaft 1 so as to push it into the prostate through, for example, the rectal wall or the perineum. Such a tab 53 may be used as the electrode is slid along the guideways of an ultrasonic scanner, as illustrated in Figure 1. A certain degree of force applied to the tab 53 may be necessary to push through the tough prostate tissue and to manipulate the exposed tip 2 to properly place it in the prostate gland.

Also shown is the connecting cable 10 and a possible separating connector 55 to

connect into the high frequency generator 11 with its monitoring apparatus as described previously in this application. The shape and configuration of the shaft 1 and tip 2 can be varied, including curved shapes, side-outlet extensions in the tip 2, round or other cross-sectional dimensions of the shaft or tip, or having side-issue, tissue-penetrating extrusions as illustrated by the Zervas type electrode available from Radionics, Inc., located in Burlington, Massachusetts.

Figure 8 shows yet another embodiment of the system and procedure according to the present invention involving the high frequency electrode 1 with its exposed tip 2 and thermosensor 35 to measure the tissue temperature or the electrode temperature during prostatic ablation. In addition, there could be a plurality of satellite temperature monitors illustrated by the probe 58 with thermal sensor 59, which is inserted trans-rectally or percutaneously into the prostate gland at a somewhat remote location to the electrode tip 2 so that tissue temperature at different locations in the prostate P can be monitored during the heating of tissue near the main tip 2. In this way, increased safety and control of the lesion process can be exercised by monitoring, at least at this point 59, the envelope of the isotherm at a distance from its core.

Also shown is a second probe 61 with a temperature sensor located at point 60 near the rectal wall in one example. This probe could be integrally formed with an ultrasonic detector or scanner 4, or could be a separate probe guided through the ultrasonic scanner or along its side. In this way the temperature of the critical structure, such as the rectal wall and mucosa layer, can be monitored by sensor 60 during the critical heating process around the electrode tip 2. Thus, the use of multiple temperature sensors, as in Figure 5, integral with the main electrode or a plurality of temperature-sensing devices located independently of the main electrode 1 can be used to increase the safety and control of the process. These electrodes have connections 10, 63, and 64, as shown in Figure 8, connected with, for example, an external monitoring apparatus 70, which could be integral or not integral with the high frequency generator. Corresponding temperature meters, 66, 67, and 68 may correspond to the monitoring of thermal sensors 35, 59, and 60, for example, so as to get a generalized view of the temperature distribution at the lesion core and remote tissue and at critical and sensitive tissues around or in the prostate.

There may be other physical approaches for placing the electrode tip 2 into the central

peri-urethral region of the prostate. For example, the perineal approach could be used involving a percutaneous approach through the perineum. The percutaneous approach is through the skin, avoiding the rectum. The electrode tip 2 could be guided by inserting an ultrasonic probe in the rectum or other guidance means such as CT, MR, or ultrasound. The ultrasonic head may provide sagittal or coronal planar views to indicate the position and orientation of the probe as it traverses the skin or rectal tissue into the prostate.

It may be possible by such visualization to place the electrode tip 2 in the medial lobe near the urethra where common urethral obstruction from benign prostatic hyperplasia (BPH) or prostatic cancer occurs. Ultrasonic guidance has the added advantage that a urologist, who typically does not perform an image scan of the prostate, may have the opportunity during the procedure to example the prostate for any other unusual signs, such as small tumors.

Thus, image guidance, which is not a part of the TURP or TUNA procedures, is an advantage for several reasons in the trans-urethral radiofrequency technique. With the present invention, if even a fraction of the urethral obstruction is eliminated, urinary obstruction may be improved substantially.

The present invention includes the process of making one or several radiofrequency (RF) ablations in the periurethral tissue. The procedure may include unilateral, bilateral, medial, or multiple longitudinal radiofrequency (RF) lesions in the prostate. Lesions in the medial lobe can be made if that is the is the site of obstruction.

The present procedure is time-efficient and cost effective. Typically an entire procedure with trans-rectal radiofrequency takes approximately 15 to 20 minutes. The instrumentation is considerably simpler than TURP or TUNA, and avoids the disadvantages and expense of a complex urological procedure such as general or epidural anesthesia, post-operative discomfort, and patient care which can extend for weeks thereafter. The procedure can be performed as an outpatient procedure with no irritation to the urethra due to scratching, as would occur in a trans-urethral approach. The present invention is thus uncomplicated, and it is simple and sure.

With image guidance, the placement of the electrode in the central region of the prostate is technically simple, and it is assured that the centrally placed ablative lesion is well away from critical structures such as the rectum, neuro-vascular bundle, and sphincter which lie at the periphery of the prostate.

It should be recognized that the present invention is aimed at making the lesion on or near the urethra itself, contrary to McGahan, et al.'s technique. As stated above, prostate cancer often occurs away from the central region of the prostate, i.e., away from the urethra, and often in the prostatic region near the rectum, so that the procedure of McGahan, et al., requires radiofrequency (RF) lesions to be made over a larger volume and region and often near the rectal wall, which is a very sensitive and critical tissue to avoid. That limitation is not inherent in the present invention in which radiofrequency (RF) lesion necroses can be made near to or on the urethra, i.e., near the central region of the prostate, with the effective result of causing a tissue cavity and urethral passage expansion.

By its nature, the present method is central and thus has the peripheral volume of the prostate as a "buffer" to help protect against damage to the rectum, for example, or the other critical structures which most often are located peripherally. Indeed studies with temperature monitoring by the present inventors confirm that the temperature near the rectal wall for lesions made near the urethra of size 1 to 2 cm remain close to normal at or near 37°C. McGahan, et al.'s technique of making radiofrequency (RF) lesions remote from the urethra or of avoiding ablating the urethral tissue itself would present a limitation and disadvantage for objectives of treating bladder outlet obstruction.

McGahan, et al.'s technique is not advantageous compared to the present invention for the treatment of benign prostatic hyperplasia (BPH). McGahan, et al.'s objective of using transrectal radiofrequency (RF) electrode prostate ablation to treat prostate carcinomas without consideration of central region and urethral radiofrequency (RF) ablation for BPH misses one of the important objectives of this present invention, which is to produce radiofrequency (RF) lesions to specifically treat BPH having locations on or near the urethra/central region. The present invention addresses use of temperature monitoring as an adjunct to making transrectal radiofrequency (RF) lesions which is also not addressed by McGahan et al. Other approaches to placement of an radiofrequency (RF) electrode are discussed herein to expand the scope of the invention.

The use of the transrectal radiofrequency (RF) electrode system herein also has advantages of simplicity, economy, control, consistency, reproducibility, and patient tolerability compared to other techniques aimed at treating BPH or prostate cancer such as TURP prostate resection, high-intensity focused ultrasound (HIFU), laser ablation, interstitial

or external radiation therapy, cryoablation, etc. The transrectal radiofrequency (RF) BPH approach is very simple and fast, since transrectal ultrasonic-guided needle passages (typically for prostate biopsy) is a common technique known to most interventional radiologists and urologists. It is easily tolerated by even the frailest of patients who may not be able to undergo a transurethral ablation or radical prostatectomy. The present approach is painless, safe, and free of acute trauma, unlike TURP, TUNA, cryosurgery, and other methods stated above because the present technique aims at the central prostate and urethra, and thus avoids the sensitive rectal mucosal tissue (which is relatively far away from the radiofrequency (RF) heat lesion).

Because it is better tolerated and less expensive than TURP, TUNA, non-central radiofrequency (RF) lesion making (viz., McGahan, et al.), or cryo-ablation, the present invention encompasses a wider population of patients and potentially will achieve more effective clinical results.

Unlike other procedures such as TURP and TUNA that heat peri-urethral tissue by passing an instrument or electrode through the urethra, the present invention approaches the central region from the rectum or skin with the aid of image guidance. This has the advantage of enabling the use of larger diameter radiofrequency (RF) electrodes (viz., 18 gauge or 0.080", or larger diameter compared to 0.010" to 0.030" for trans-urethra electrodes in TUNA) which produce larger ablative volumes, and of visualizing in real time the positioning of the radiofrequency (RF) electrodes near the urethra, away from the urethra sphincter and apex and to be sure it is placed centrally near the obstructive region. It also has the advantage of being less expensive than the TURP or TUNA procedures, as only simple electrodes are required.

Forms and embodiments of the transrectal radiofrequency (RF) urethral ablation system and method are provided involving various electrode designs with and without temperature monitoring and in various electrode geometries. However, it should be recognized that other obvious forms may be used.

In view of these considerations, as would be apparent by persons skilled in the art, implementations and systems should be considered broadly and with reference to the claims set forth below.

What is claimed is:

1. A method of inducing trans-rectal or percutaneous urethral enlargement of the prostate in an operative field in a patient, which includes a peri-urethral region of the prostate, comprising the steps of:

inserting an electrode into the peri-urethral tissue within said operative field proximate or on the urethra utilizing a trans-rectal or a percutaneous approach;

connecting said electrode to a high frequency generator located external to said operative field;

utilizing said high frequency generator to generate a high frequency output; and

applying an appropriate level of said high frequency output from said high frequency generator through said electrode to induce heat ablation of the peri-urethral tissue within said operative field to a desired degree of ablation and thereby induce formation of a cavity, which enlarges a passageway within the urethra.

2. The method of Claim 1 and further comprising the step of:

monitoring the position of said electrode in the peri-urethral tissue within said operative field by an ultrasonic scanner inserted in the rectum of said patent.

3. The method of Claim 1 and further comprising the step of:

generating image representations of said electrode for guiding said electrode in the peri-urethral tissue in said operative field with a CT or an MR imaging scanner.

4. The method of Claim 1 further comprising the step of:

detecting a temperature level of the peri-urethral tissue with a temperature sensor in said electrode coupled to an external temperature monitor.

5. A method of including urethral enlargement in the prostate within an operative field of a patient comprising the steps of:

inserting an electrode into the central region of the prostate in said operative field near the urethra;

generating image representations of the position of said electrode in the prostate by utilizing an imaging apparatus;

connecting said electrode to a high frequency generator located external to said operative field; and

heating said central region of the prostate within said operative field by applying an output from said high frequency generator to the tissue within said operative field through said electrode sufficient to elevate a portion of the tissue in said central region to at least 50°C to induce ablation of the portion of the tissue in the central region of said operative field and thereby cause enlargement of the urethral passageway.

6. The method of Claim 5 wherein said generating step comprises inserting an ultrasonic image scanner into the rectum of the patient to visualize the prostate and the position of said electrode within the central region of said operative field.

7. The method of Claim 5 wherein said generating step comprises scanning said patient by a CT or MR image scanner to visualize the prostate and the position of said electrode within the central region of said operative field.

8. A method of relieving urethral obstruction in a patient with benign prostatic hypertrophy comprising the steps of:

inserting through a rectal wall an electrode into the prostate of a patient, the electrode having a tip which is uninsulated and has an electrical connection for connecting said tip to a high frequency generator located external to the body of the patient;

disposing the uninsulated tip near the urethra close to the point of urethral obstruction;

locating a an ultrasonic imaging detector near the rectal wall of the patient;

generating ultrasonic images of said tip and its position near the urethra with said ultrasonic imaging detector; and

heating the prostate tissue near the urethra by connecting said tip of said

electrode to the high frequency generator and inducing ablative reduction of tissue mass near the urethra to reduce the urethral obstruction.

9. The method of Claim 8 wherein said tip of said electrode has a surface which is roughened to enhance its detectability characteristics by ultrasonic imaging.

10. A system for high frequency heating of an operative field comprising the prostate of a patient for the enlargement of the urethra, comprising:

a generator of high frequency output;

an electrode adapted to penetrate the prostate having an electrically conductive tip, the tip having a tissue-piercing, sharpened distal point, said electrode having an elongated shaft which is in part electrically insulated, said shaft having a length of at least 200 mm to enable penetration of said tip to about the central region of said prostate through the rectum or the skin of said patient; and

an electrical connection between said conductive tip and said generator so that said high frequency output of said generator can induce heating of a portion of said prostate when said tip is placed in the prostate in said operative field thereby causing urethral enlargement.

11. The system of Claim 10 and further including a hub on said electrode which is fixable to said electrode and which has a configuration to enable gripping of said hub by the fingers of a clinician so that longitudinal forces on the electrode can urge its entry into the prostate in said operative field.

12. The system of Claim 10 wherein said electrode includes a temperature sensor to sense the temperature of the prostate during heating, and an external apparatus coupled to the temperature sensor to monitor the temperature as measured by said temperature sensor.

13. The system of Claim 10 and including a temperature sensing probe which can be inserted into or adjacent to said prostate to sense the temperature of said tissue at a distance from said tip when said heating is taking place, and external apparatus to monitor the

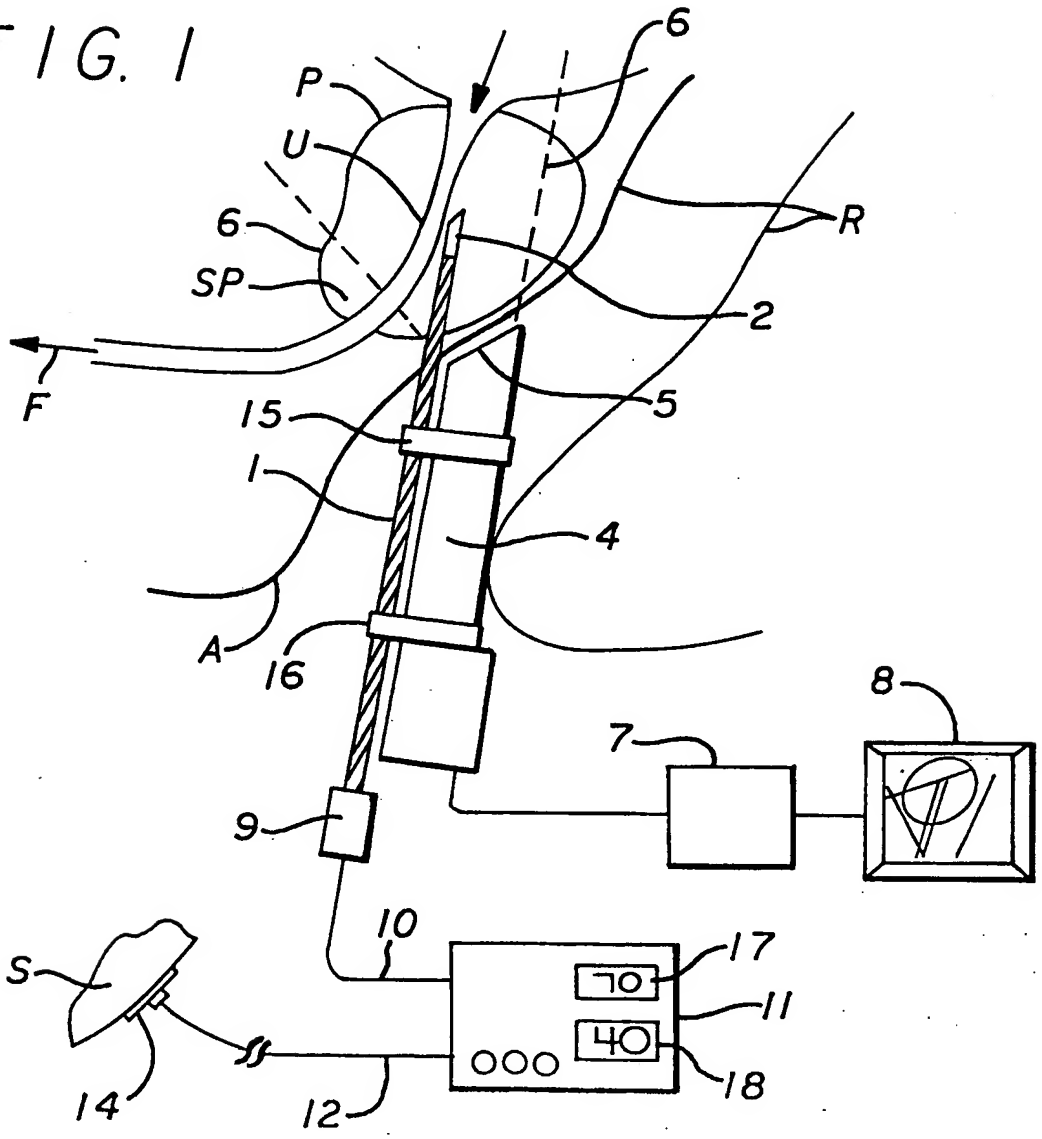
temperature as sensed by said temperature sensor probe.

14. The apparatus of Claim 10 and further including an image scanner to monitor the placement of said tip in the prostate.

15. The apparatus of Claim 14 wherein said image scanner is an ultrasonic scanner adapted to be inserted in the rectum of the patient.

16. The apparatus of Claim 13 wherein said temperature sensor is adapted to be placed in or adjacent to the rectal wall to monitor the temperature of the rectal wall during said heating.

FIG. 1



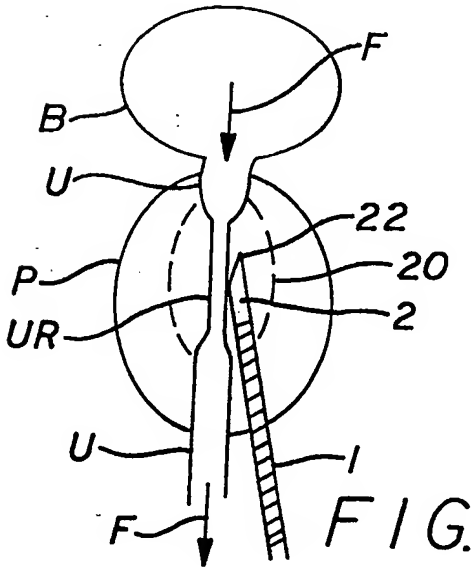


FIG. 2

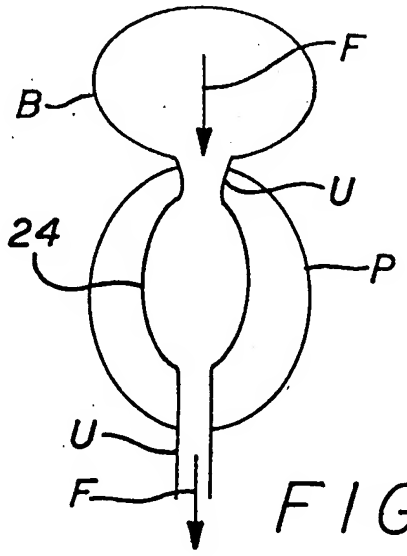


FIG. 3

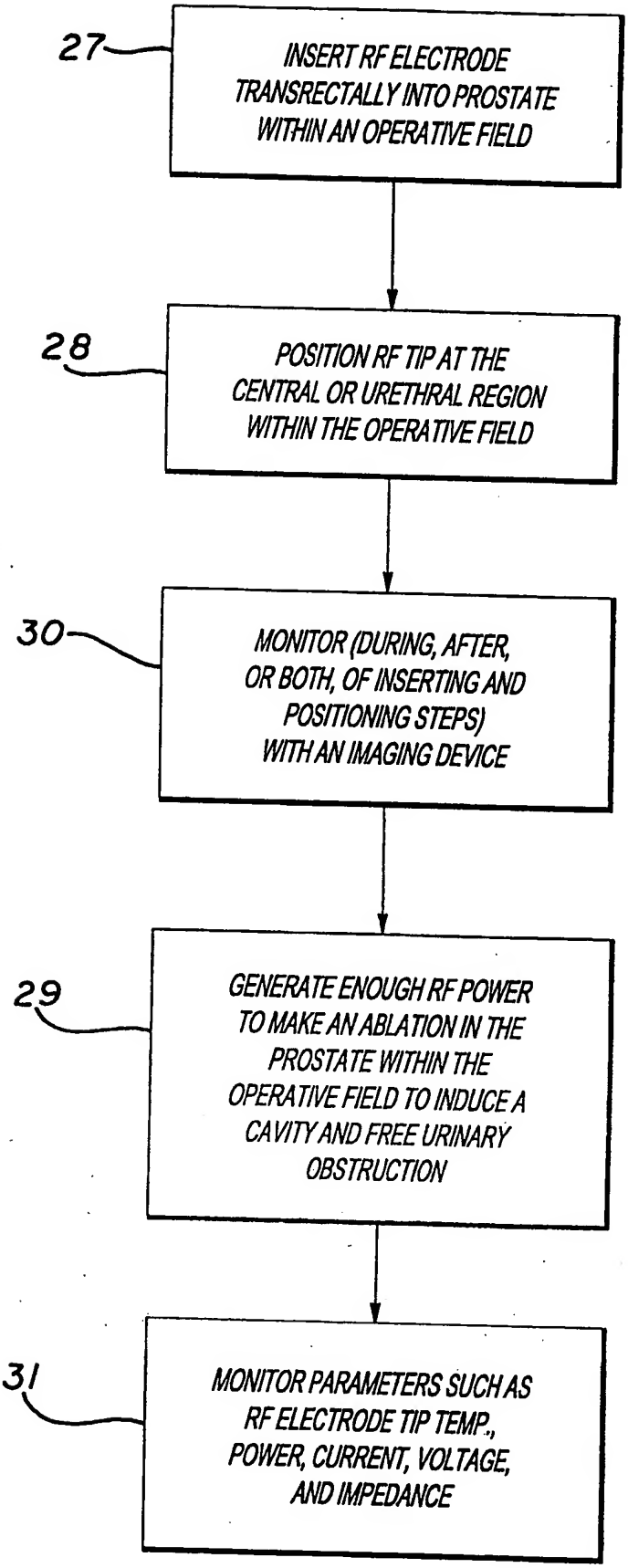

27
INSERT RF ELECTRODE TRANSRECTALLY INTO PROSTATE WITHIN AN OPERATIVE FIELD
28
POSITION RF TIP AT THE CENTRAL OR URETHRAL REGION WITHIN THE OPERATIVE FIELD
30
MONITOR (DURING, AFTER, OR BOTH, OF INSERTING AND POSITIONING STEPS) WITH AN IMAGING DEVICE
29
GENERATE ENOUGH RF POWER TO MAKE AN ABLATION IN THE PROSTATE WITHIN THE OPERATIVE FIELD TO INDUCE A CAVITY AND FREE URINARY OBSTRUCTION
31
MONITOR PARAMETERS SUCH AS RF ELECTRODE TIP TEMP., POWER, CURRENT, VOLTAGE, AND IMPEDANCE

FIG. 4

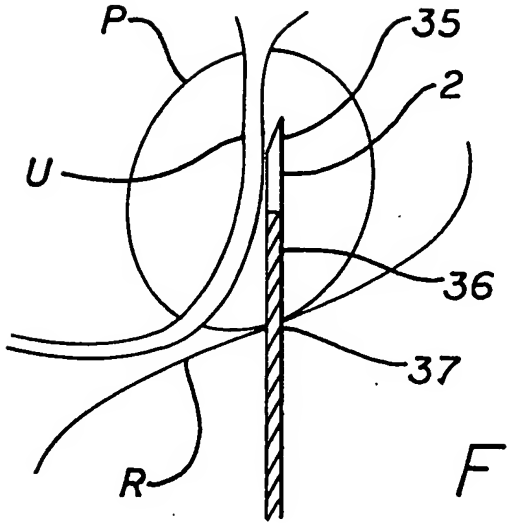


FIG. 5

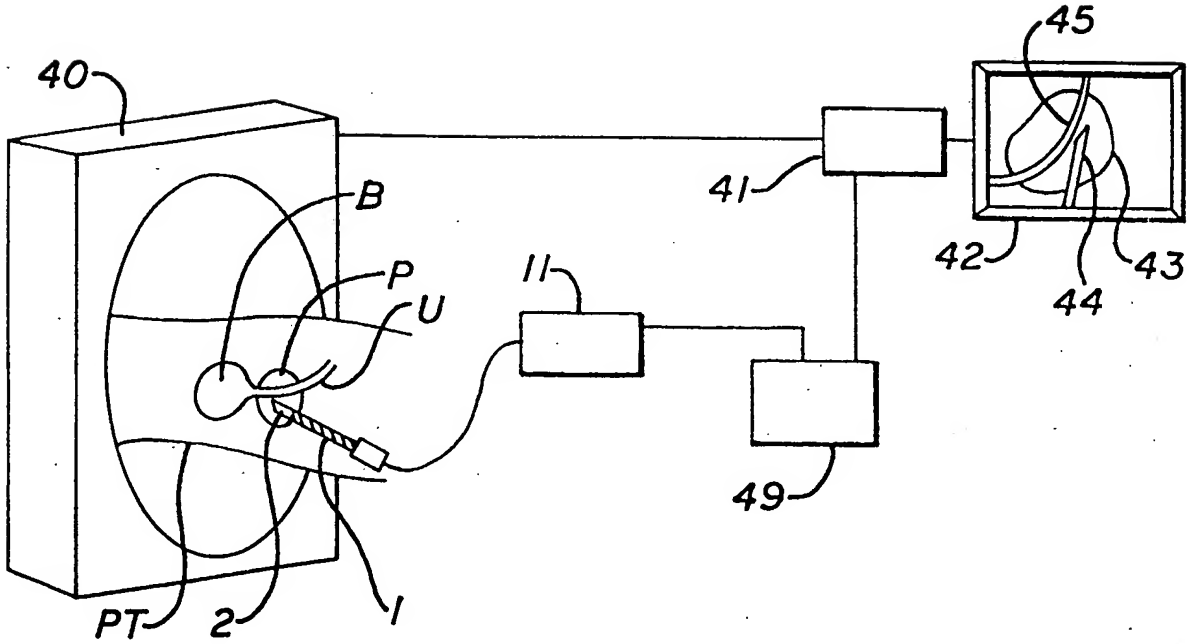


FIG. 6

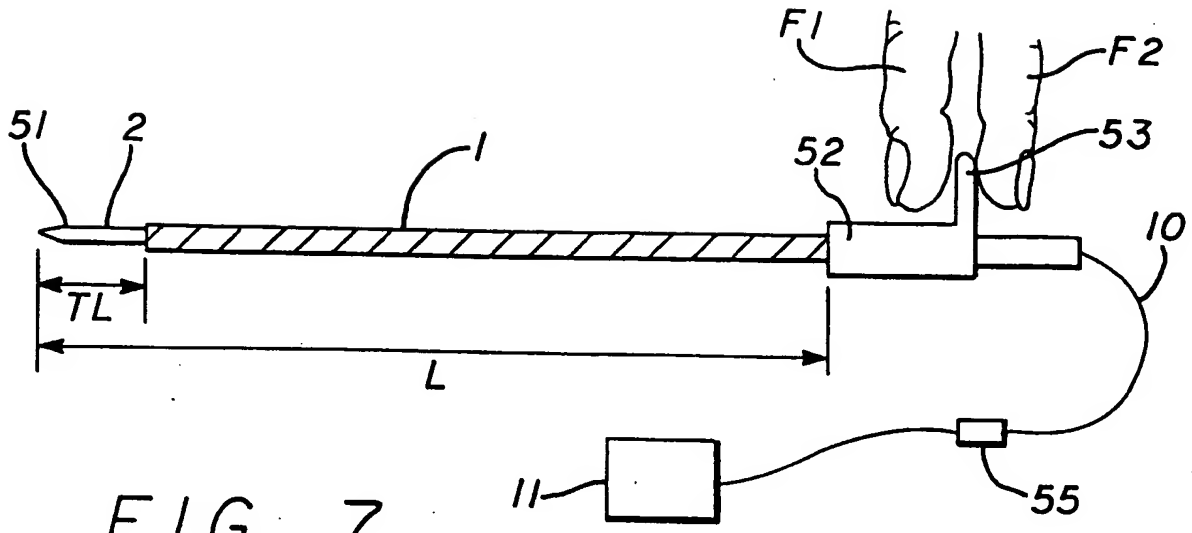

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FIG. 7

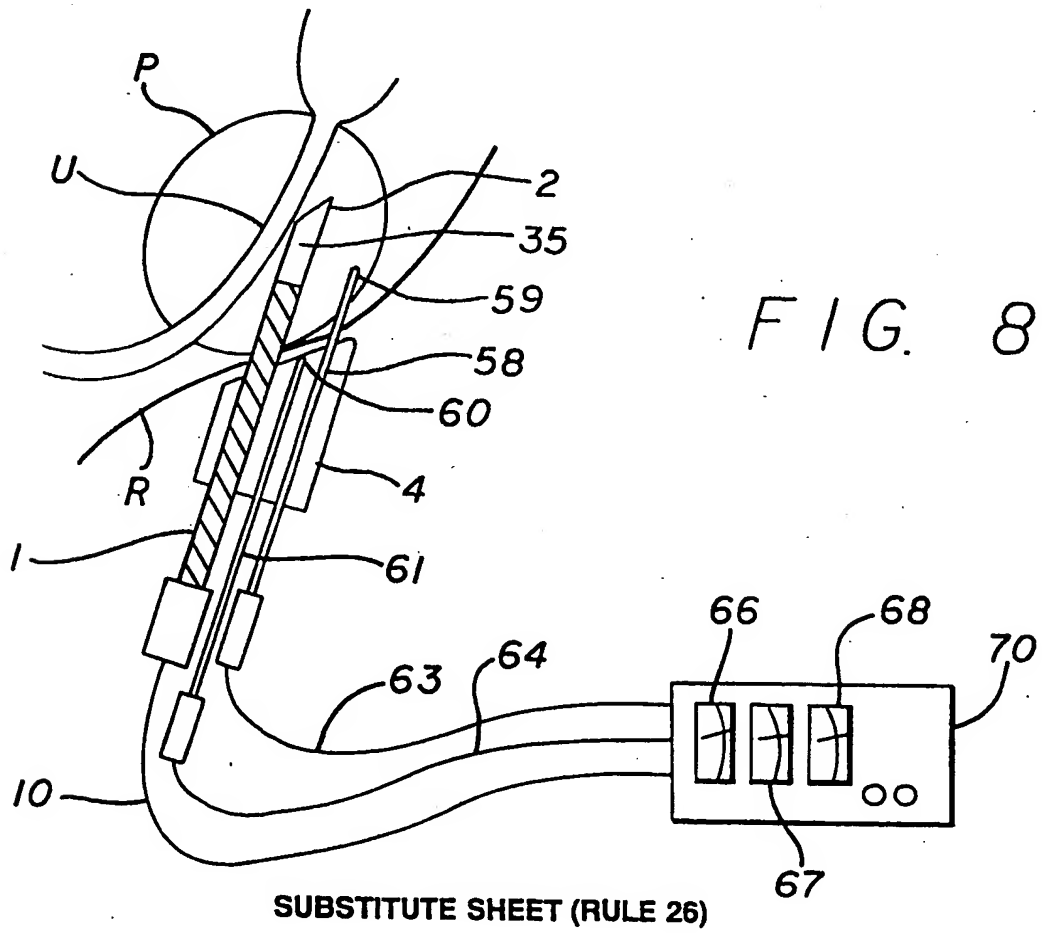
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FIG. 8

INTERNATIONAL SEARCH REPORT

Interna...nal Application No
PCT/US 98/07419

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 486 161 A (LAX RONALD G ET AL) 23 January 1996 see column 6, line 12 - column 7, line 28; figures 7-10 ---	10,11
A	US 5 599 294 A (LUNDQUIST INGEMAR H ET AL) 4 February 1997 see abstract; figures 1,2 ---	10,12-16
A	WO 96 37158 A (CHINN DOUGLAS O) 28 November 1996 see page 8, line 23 - page 10, line 22; figures 1-3 ---	10,13-16
A	US 5 542 915 A (LUNDQUIST INGEMAR H ET AL) 6 August 1996 see abstract; figure 1 --- -/--	10,12,14

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 July 1998	4 August 1998 (04.08.98)

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

INTERNATIONAL SEARCH REPORT

Interna..nal Application No
PCT/US 98/07419

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 599 346 A (BAKER JAMES ET AL) 4 February 1997 see column 7, line 46 - line 55; figure 3 -----	10,12

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No
PCT/US 98/07419

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5486161 A	23-01-1996	US 5370675 A	06-12-1994
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